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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,959	02/25/2004	William Toreki	QMT1.1-CIP2-US	4101

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/786,959	TOREKI ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60,61 and 63-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60,61 and 63-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/06/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 60-61,63-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batich et al. (US 2002/0177828) in view of Schoenfeldt et al. (US 2002/0172708) and in further view of Voorhees et al. (US 2004/0235950 A1), for the reasons set forth in the office action mailed 05/04/2006.

Applicant's arguments filed 11/21/2006 have been fully considered but they are not persuasive.

Applicants asserts firstly that the subject matter of claims 66-68,70-71 and 72 are not met by Batich because Batich fails to disclose all of the elements of applicants

invention because he does not disclose a wound dressing with a matrix metalloproteinase inhibitor or an antibiotic, analgesic, anti-inflametory or combination thereof.

The examiner would like to clarify that specific limitations within the claims are met by Batich, but not all of the claim limitations, if Batich met all the limitations by itself there wouldn't be a need to combine the Batich reference with the other two references. The examiner merely stated that the specific limitations within the claims are met, specifically the polyionic polymer is diallyldimethylammonium chloride and the substrate further comprises a hemostatic agent are both met by the disclosure of Batich. The other references are relied upon for the other limitations. The examiner hopes this explanation clarifies the office action; that is Batich meets the limitations above but not all of the limitations in the claims or the entire claims themselves and the examiner did not intend applicants to interpret the office action as stating that Batich meets all the limitations in claims 66-68,70-71 and 72.

Applicants assert that none of the prior art references in the office action disclose or suggest ionically associating metalloproteinase inhibitors or an antibiotic, analgesic, anti-inflammatory or combination thereof with a polyionic polymer covalently bonded to a substrate to achieve extended release. Applicants further state that there is no discussion within Voorhees of combining the metalloproteinase inhibitors with polycationic polymers. Applicants furhter state that Schoenfeldt lacks the element of extended release and that Schhoenfeldt teaches that a pharmaceutical medicament may participate in crosslinking thus the medicament would be insoluble and therefore

unreleasable. Applicants state that Voorhees does not disclose or suggest ionically associating MMP inhibitor with a polyionic polymer and that there no suggestion that GM1489 can ionically associate. Because of the deficiencies above the applicants assert that there is no reason for an expectation of success in combining Schoenfeldt and Voorhees with Batich. Applicants lastly assert that the examiner has effectively used applicants invention to combine references with the benefit of impermissible hindsight and vision afforded by the claimed invention.

The relevance of these assertions is unclear. Firstly Batich as disclosed in the previous office action wound discloses a dressing comprising all of the ingredients claimed by applicant except the use of metalloproteinase inhibitors, while Schoenfeldt discloses an absorbing article containing polyionic polymers and metalloproteinase inhibitors and Voorhees was used only for the disclosure on acne treatment (topical) comprising the specific MMP GM 1489. Since all of the references are used in combination in a 103(a) rejection one reference does not have to disclose all of applicants claimed invention if it would have been obvious to one skilled in the art to combine the above references at the time of the invention. The Batich and Schoenfeldt references are both related as materials useful in treating wounds containing polyionic polymers, Batich discloses all of applicants invention except for the use of the specific actives metalloproteinase inhibitors while Schoenfeldt discloses the use of polyionic polymers and metalloproteinase inhibitors in combination. Regarding applicants assertion that Schoenfeldt lacks the element of extended release, the examiner disagrees, the combination of Batich and Schoenfeldt would meet all of the limitations

disclosed by applicant (a polyionic polymer in combination with an MMP), therefore the limitation is met by the combination of references because the same composition will have the same properties such as extended release. Since Schoenfeldt discloses the use of polyionic polymers in combination with MMPs the association will be the same in the Schoenfeldt reference as it is in applicants claimed invention. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding applicants assertion that the medicament may participate in crosslinking, this is just one embodiment of the Schoenfeldt invention and is not limiting the scope of the entire invention and the word "may" is also not limiting the scope. The Voorhees reference was only used to show that the use of the specific metalloproteinase inhibitors GM 1489 was known at the time of the invention to be used in topical applications and not for disclosing a wound dressing and since Schoenfeldt already discloses the use of polyionic polymers and metalloproteinase inhibitors in combination one skilled in the art would know that numerous specific examples of the metalloproteinase inhibitors such as GM 1489 could be used as the active because GM 1489 is just a species of the same genus (MMP) disclosed in Schoenfeldt. The combination of Batich, Schenfeldt and Voorhees would lead to a method for the treatment of skin wounds comprised of contacting skin with a substrate covalently bonded to polyionic polymers ionically associated with

metalloproteinase inhibitors such as GM 1489. The examiner also disagrees with applicants assertion that there is no expectation of success in combining the three references above and the examiner used the benefit of impermissible hindsight and vision afforded by the claimed invention. As already described Batich discloses all of applicants invention except for the specific active MMP, one skilled in the art could envision the use of other actives and would readily find the Schoenfeldt reference while searching for polyionic polymers in combination with pharmaceutical medicaments and that they could use MMPs in combination with polyionic polymers and could further find specific MMPs such as those disclosed within Voorhees. One skilled in the art would have a reasonable expectation of success in combining the above references to provide a method for treating skin conditions by applying a substrate comprising a polyionic polymer bond to that substrate (disclosed in Batich) and a sufficient quantity of an MMP inhibitor (disclosed in Schoenfeldt) including the specific MMP GM 1489 (disclosed in Voorhees).

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER